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Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on the HPV Test Plan for 4-Nitro-N-Methylphthalimide

Dear Administrator Whitman:

The following comments on the General Electric Company (GE) High Production Volume (HPV) Chemicals Challenge Program test plan for 4-Nitro-N-Methylphthalimide (4-NPI) are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

4-NPI (CAS RN 41663-84-7) is one of three test plans submitted by Toxicology/Regulatory Services, Inc. on behalf of GE on December 30, 2002. According to their robust summary, 4-NPI is a site-limited intermediate that is made at a single location and 99.95% of the product is used as a reactive intermediate in high molecular weight polyetherimide polymers. The other 0.05% is sold as a reactive intermediate to make industrial adhesive. GE has proposed performing a reproductive toxicity test on PI, because no data could be located for this endpoint. The specific OECD Test Guideline to be conducted was not provided.

We appreciate GE's comprehensive literature search and agree that further animal testing is not needed for any other toxicity endpoint. However, we are perplexed by the lack of information given in GE's test plan and robust summary in regards to two critical issues: closed-system intermediate status of 4-NPI and specific OECD Test Guideline proposed.

Depending on the content of the missing information, the perceived need for reproductive testing to meet this SIDS data requirement may not be valid. Although GE does not provide enough precise information that would allow us to substantiate this conclusion, it is certainly possible, given that 4-NPI is an intermediate made at a single location in the US and only a very small percentage actually leaves that location, that it qualifies as a closed-system

intermediate[1]. We urge GE to examine this document to determine if in fact 4-NPI fits the qualifications of a closed-system intermediate, and submit information certifying this to the EPA. Failure to do this, if in fact 4-NPI does qualify as a closed-system intermediate, would be a violation of the October 14, 1999 letter sent to participants stating that, per the OECD guidelines, "participants shall not develop sub-chronic or reproductive toxicity data for the HPV chemicals that are solely closed system intermediates."

If GE determines that reproductive toxicity testing is in fact required in order to meet the EPA requirements of the HPV program, it would still be in violation of the above agreement, which requires participants to "minimize further testing." The proposed test, assuming they are planning to perform OECD Test Guideline 415 (1 generation reproduction) will involve the suffering and death of at least 1,300 animals. While we hope that GE will agree that no further animal testing should be conducted on 4-NPI, at the very least GE should propose OECD Test Guideline 422 (combined developmental/repro/repeat dose). This would reduce the suffering and death caused by this test plan by half. GE must therefore clarify its test plan to reflect the use of a minimum number of animals.

PCRM and other commenters have repeatedly brought to the EPA's attention violations of the October 1999 agreement, only to be ignored. This is yet another example of a GE test plan that is in violation of this agreement. We request that the EPA give GE guidance regarding both the aforementioned agreement and policies on closed-system intermediates, in order to minimize substantially the numbers of animals who will suffer as a result of this proposed test plan.

Thank you for your attention to these comments. I look forward to a prompt and favorable response to our concerns. I may be reached at 202-686-2210, ext. 335, or via email at *kstoick@pcrm.org*.

Sincerely,

Kristie Stoick, MPH
Research Analyst

Chad Sandusky, PhD
Director of Research

[1]U.S. Environmental Protection Agency (EPA) document entitled Guidance for Testing Closed System Intermediates for the HPV Challenge Program, February 8, 1999.